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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,628	10/06/2000	G. Grady McBride	5259-04700	1875

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/684,628

Applicant(s)

MCBRIDE ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-32, 36, 39-56, 59-67, 69-84, 86-98 and 286 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70-84, 86-98 and 286 is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-32, 39, 42-55, 59-67, 69 is/are rejected.
- 7) ☒ Claim(s) 36, 40, 41 and 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/24/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 24, 2004 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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3. Claims 1, 2, 5, 8-11, 14, 20, 21, 23-25, 27-32, 37, 39, 42, 43, 46, 48, 57, 59, 65, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. (5,688,272) in view of Freid et al. (6,331,179). Montague discloses the invention substantially as claimed. Montague discloses, in figures 6 and 7, a connector (204) or transverse connector (of bone or the spine) for an elongated member (R) having a body (30), a first opening (32) in the body configured to hold the elongate member, an engager (47) with a surface of a cam system (40, 43) or an engaging mechanism (40, 43) with a portion (40) angulated within the body substantially perpendicular to a longitudinal axis of the body, and a cam system opening (37) in communication with the first opening, where removal of the cam system is inhibited by threads (at 37), and where a drive tool (e.g., an Allen head wrench—see col. 9, lines 5-10) is used to rotate the cam system (at the engager). However, Montague et al. do not specifically disclose the rotation ranges of the cam system as claimed. Nevertheless, it would have been a matter of design choice to dimension the engaging mechanism, so that the cam system has a rotation range of claimed. Such a choice would be dependent upon the size of an elongated member required for a surgical procedure. Also, Montague et al. do not disclose that the drive tool has a visual indicator that informs a user that the cam system is engaged, and that a handle of the drive tool has an elongated portion that is substantially aligned with the elongated member when the transverse connector is coupled to the elongated member. Freid et al. teach, in fig. 22, a drive tool (450) with an elongated handle (454) that is a visual indicator. It would have been obvious to one

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having ordinary skill in the art at the time the invention was made, in view of Freid et al., to include a drive tool with a visual indicator with the connector of Montague et al. Such a tool would not only allow a user to activate the cam system, it would also allow a user to visually gauge the level of engagement of the cam system with the elongated member (by viewing of the handle as the tool is used), and it would be a matter of design choice to substantially align the handle with the elongated member when the transverse connector is coupled to the elongated member. The choice of such a visual gauge would be dependent upon the dimensions of the connector and the elongated member being engaged (dimensions that would affect the amount of rotation of the drive tool).

4. Claims 1, 15-19, 22, 42, 45, 49-52, 54, 60-64, 67, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Troxell et al. (6,283,967) in view of Freid et al. (6,331,179). Troxell et al. discloses the invention substantially as claimed. Troxell et al. disclose, in the figures, a connector, where the connector includes a substantially unbendable (but bendable, nonetheless) body (10) with first and second sections (16, 18), an indentation (32), and a fastening system (44) or fastener, first and second openings (at 22 and 26) in the body for receiving elongated members (12, 14), and a cam system (94) in communication with the first opening, positioned between the first and second openings, and configured to rotate or extend an engager (102) into the first opening, and a cam system opening (92), where the longitudinal axis of the cam system is substantially perpendicular to the longitudinal axis of the body, where the connector is a transverse connector of a bone or spinal stabilization system, and where the position

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of cam system within the cam system opening gives a visual indication of engagement.

However, Troxell et al. do not specifically disclose the rotation ranges of the cam system as claimed and distances between elongated members as claimed.

Nevertheless, it would have been a matter of design choice to dimension the transverse connector, so that the cam system has a rotation range of claimed. Such a choice would be dependent upon the size of an elongated member required for a surgical procedure. Also, it would have been a matter of design choice to dimension the connector, so that the distances between elongated members are as claimed. The choice would be dependent upon the dimensions and location of the surgical site receiving the connector. Also, Troxell et al. do not disclose that the drive tool has a visual indicator that informs a user that the cam system is engaged. Freid et al. teach, in fig. 22, a drive tool (450) with a handle (454) that is a visual indicator. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Freid et al., to include a drive tool with a visual indicator with the connector of Troxell et al. Such a tool would not only allow a user to activate the cam system, it would also allow a user to visually gauge the level of engagement of the cam system with the elongated member (by viewing of the handle as the tool is used).

5. Claims 4, 27, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. in view of Freid et al., and further in view of Tornier et al (5,662,651). Montague et al. in view of Freid et al. disclose the invention substantially as claimed, but do not disclose a connector with an opening surface that contacts an elongated member, where the surface is textured. Tornier et al. teach, in figure 1, a

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connector (3) with a textured surface (3d) for contacting an elongated member. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Tornier et al., to texturize the opening surface of the connector of Montague et al. in view of Freid et al. Such a modification would make for a more secure connection (without rotation of the elongated member) between the connector and elongated member.

6. Claims 3, 26, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. in view of Freid et al. as applied above, and further in view of Ralph et al (5,752,957). Montague et al. in view of Freid et al. disclose the invention substantially as claimed, but do not disclose that the engager comprises a surface with a portion that is textured. Ralph et al. teach, in figure 9, an engager (180) with a textured surface for engagement with an elongated member (202). It would have been obvious to one having ordinary skill in the art at the time the invention was made, to employ an engager with a textured surface in the connector of Montague et al. in view of Freid et al. Such an engager, upon engagement with the elongated member, would have a stronger grip.

7. Claims 6, 7, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. in view of Freid et al. as applied above, and further in view of Drummond et al (6,113,600). Montague et al. in view of Freid et al. disclose the invention substantially as claimed, but do not disclose a portion of the cam system that is angulated within the body at an angle greater than about 45 deg. or 60 deg. relative to the longitudinal axis of the body. Drummond et al. teach, in figures 2-5 and in col. 5,

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lines 6-18, cam system (16) that is angulated within a body at an angle greater than about 45 deg. or 60 deg. relative to the longitudinal axis of the body. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Drummond et al. to modify the connector of Montague et al. in view of Freid et al. , so that the cam system is angulated within a body at an angle greater than about 45 deg. or 60 deg. relative to the longitudinal axis of the body. Such a modification would not only allow top-tightening of the cam system (and reduce the size of the surgical site for implantation of the body), it would allow reduction of the cross-sectional profile of the body for easier implantation into a patient.

Allowable Subject Matter

8. Claims 70-84, 86-98, and 286 are allowed.
9. None of the prior art of record, alone or in combination, discloses, inter alia, a connector with a body, an engager, a cam system, and a first opening in the body for holding an elongated member, where the connector includes a vibrational indicator that the cam system is engaged with an elongated member coupled to the body and where a fastening system for sections of the connector body comprises a collet and a collar.
10. Claims 36, 40, 41, and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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11. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses, inter alia, a connector with a body, an engager, a cam system, first and second elongated members, and first and second fixation elements, where the connector includes a vibrational or pin indicator that the cam system is engaged with the body, and where the opening has an open side that allows an elongated member to be top loaded onto the connector.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

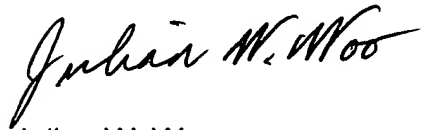
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo
Primary Examiner

February 17, 2005